

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claims 1-27. (cancelled)

Claim 28. (Currently amended) A pharmaceutical composition for parenteral administration, comprising:

a therapeutically effective amount of a protein or polypeptide selected from the group consisting of Factor VIIa for treating trauma bleeding in hemophilia patients, granulocyte colony-stimulating factor (G-CSF), granulocyte macrophage colony-stimulating factor (GM-CSF), interferon γ , glucagon-like peptide 1 (GLP-1), and Cepaxone glatiramer acetate; and

one or more colloidal particles comprising approximately 1-20 mole percent of an amphipathic lipid derivatized with a biocompatible hydrophilic polymer, wherein the protein or polypeptide is non-covalently bound to the one or more colloidal particles and the protein or polypeptide is not encapsulated in the one or more colloidal particles.

Claim 29. (Previously presented) The pharmaceutical composition of claim 28, wherein the colloidal particles are substantially neutral and the polymer carries substantially no net charge.

Claim 30. (Previously presented) The pharmaceutical composition of claim 28, wherein the colloidal particles have a mean particle diameter of between about 0.03 to about 0.4 microns.

Claim 31. (Previously presented) The pharmaceutical composition of claim 30, wherein the colloidal particles have a mean particle diameter of approximately 0.1 microns.

Claim 32. (Previously presented) The pharmaceutical composition of claim 28, wherein the amphipathic lipid is a phospholipid from natural or synthetic sources.

Claim 33. (Previously presented) The pharmaceutical composition of claim 32, wherein the amphipathic lipid is phosphatidylethanolamine (PE).

Claim 34. (Previously presented) The pharmaceutical composition of claim 28, wherein the amphipathic lipid is a carbamate-linked uncharged lipopolymer.

Claim 35. (Previously presented) The pharmaceutical composition of claim 28, wherein the amphipathic lipid is aminopropanediol distearoyl (DS).

Claim 36. (Previously presented) The pharmaceutical composition of claim 28, wherein the colloidal particles further comprise a second amphipathic lipid obtained from either natural or synthetic sources.

Claim 37. (Previously presented) The pharmaceutical composition of claim 36, wherein the second amphipathic lipid is phosphatidylcholine.

Claim 38. (Previously presented) The pharmaceutical composition of claim 36, further comprising cholesterol.

Claim 39. (Previously presented) The pharmaceutical composition of claim 28, wherein the biocompatible hydrophilic polymer is selected from the group consisting of polyalkylether, polylactic and polyglycolic acid families.

Claim 40. (Previously presented) The pharmaceutical composition of claim 39, wherein the biocompatible hydrophilic polymer is polyethylene glycol.

Claim 41. (Previously presented) The pharmaceutical composition of claim 40, wherein the polyethylene glycol has a molecular weight of between about 500 to about 5000 daltons.

Claim 42. (Previously presented) The pharmaceutical composition of claim 41, wherein the polyethylene glycol has a molecular weight of approximately 2000 daltons.

Claims 43-44. (Cancelled)

Claim 45. (Withdrawn) The pharmaceutical composition of claim 28, wherein the polypeptide is Factor VIIa, and the composition may be used with inhibitors for the treatment of trauma bleeding in hemophilia patients.

Claim 46. (Cancelled)

Claim 47. (Currently amended) A method for treating a patient suffering from multiple sclerosis, comprising administering to the patient a pharmaceutical composition for parenteral administration comprising a therapeutically effective amount of Gepaxone glatiramer acetate non-covalently bound to one or more colloidal particles, the one or more colloidal particles comprising approximately 1-20 mole percent of an amphipathic lipid derivatized with a biocompatible hydrophilic polymer,

wherein the Gepaxone glatiramer acetate is not encapsulated in the one or more colloidal particles.

Claims 48-49. (Canceled)

Claim 50. (Currently amended) A method for treating a patient suffering from a disease that is known to be treatable with Gepaxone glatiramer acetate, comprising administering to a patient in need thereof a therapeutically effective amount of

Cepaxone glatiramer acetate; and

one or more colloidal particles comprising approximately 1-20 mole percent of an amphipathic lipid derivatized with a biocompatible hydrophilic polymer,
wherein the one or more colloidal particles and Cepaxone glatiramer acetate are administered separately.

Claims 51-52. (Cancelled)

Claim 53. (Previously presented) The method of claim 50, wherein the amphipathic lipid is selected from the group consisting of phosphatidylethanolamine (PE), a carbamate-linked uncharged lipopolymer and aminopropanediol distearoyl (DS).

Claim 54. (Previously presented) A method for treating a patient suffering from hemophilia, comprising:

administering to a patient in need thereof a pharmaceutical composition for parenteral administration comprising a therapeutically effective amount of Factor VIIa non-covalently bound to one or more colloidal particles, the one or more colloidal particles comprising approximately 1-20 mole percent of an amphipathic lipid derivatized with a biocompatible hydrophilic polymer,

wherein Factor VIIa is not encapsulated in the colloidal particles.

Claims 55-56. (Cancelled)

Claim 57. (Currently amended) A method for extending the half-life of a protein or polypeptide in vivo, comprising:

providing a pharmaceutical composition for parenteral administration comprising a therapeutically effective amount of the protein or polypeptide non-covalently bound to one or more colloidal particles, the one or more colloidal particles comprising approximately 1-20 mole percent of an amphipathic lipid derivatized with a biocompatible hydrophilic polymer, the protein or polypeptide is selected from the group consisting of granulocyte colony-stimulating factor (G-CSF), granulocyte macrophage colony-stimulating factor (GM-CSF), interferon γ , glucagon-like peptide 1 (GLP-1) and Gepaxone glatiramer acetate; and

administering the pharmaceutical composition to a patient,

wherein the protein or polypeptide is not encapsulated in the colloidal particles.

Claim 58. (Previously presented) A pharmaceutical composition for treating trauma bleeding in hemophilia patients via parenteral administration, comprising:

a therapeutically effective amount of Factor VIIa; and
one or more colloidal particles comprising approximately 1-20 mole percent of an amphipathic lipid derivatized with a biocompatible hydrophilic polymer,

wherein Factor VIIa is non-covalently bound to the one or more colloidal particles and Factor VIIa is not encapsulated in the one or more colloidal particles.

Claim 59. (Currently amended) A pharmaceutical composition for parenteral administration, comprising:

a therapeutically effective amount of a protein or polypeptide selected from the group consisting of Factor VIIa, granulocyte colony-stimulating factor (G-CSF), granulocyte macrophage colony-stimulating factor (GM-CSF), interferon γ , glucagon-like peptide 1 (GLP-1) and Gepaxone glatiramer acetate; and

one or more colloidal particles having a mean particle diameter of from 0.03 to 0.4 microns, the one or more colloidal particles comprising approximately 1-20 mole percent of an amphipathic lipid derivatized with a biocompatible hydrophilic polymer,

wherein the protein or polypeptide is non-covalently bound to the one or more colloidal particles.

Claim 60. (Previously presented) The pharmaceutical composition of claim 59, wherein the amphipathic lipid is selected from the group consisting of phosphatidylethanolamine (PE), a carbamate-linked uncharged lipopolymer and aminopropanediol distearoyl (DS).

Claim 61. (Previously presented) The pharmaceutical composition of claim 60, wherein the amphipathic lipid is aminopropanediol distearoyl (DS).

Claim 62. (Previously presented) The pharmaceutical composition of claim 60, wherein the biocompatible hydrophilic polymer is selected from the group consisting of polyalkylether, polylactic and polyglycolic acid families.

Claim 63. (Previously presented) The pharmaceutical composition of claim 61, wherein the biocompatible hydrophilic polymer is polyethylene glycol.

Claim 64. (Currently amended) A pharmaceutical composition for parenteral administration, comprising:

a therapeutically effective amount of a protein or polypeptide selected from the group consisting of granulocyte colony-stimulating factor (G-CSF), granulocyte macrophage colony-stimulating factor (GM-CSF), interferon γ , glucagon-like peptide

1 (GLP-1) and Gepaxone glatiramer acetate; and

one or more colloidal particles comprising approximately 1-20 mole percent of an amphipathic lipid derivatized with a biocompatible hydrophilic polymer,

wherein the protein or polypeptide is non-covalently bound to the one or more colloidal particles and the protein or polypeptide is not encapsulated in the one or more colloidal particles.

Claim 65. (Currently amended) The pharmaceutical composition of claim [[63]] 64, wherein the amphipathic lipid is selected from the group consisting of phosphatidylethanolamine (PE), a carbamate-linked uncharged lipopolymer, and aminopropanediol distearoyl (DS).

Claim 66. (Previously presented) The pharmaceutical composition of claim 65, wherein the amphipathic lipid is aminopropanediol distearoyl (DS).

Claim 67. (Previously presented) The pharmaceutical composition of claim 65, wherein the biocompatible hydrophilic polymer is selected from the group consisting of polyalkylether, polylactic and polyglycolic acid families.

Claim 68. (Previously presented) The pharmaceutical composition of claim 67, wherein the biocompatible hydrophilic polymer is polyethylene glycol.

Claim 69. (Previously presented) The pharmaceutical composition of claim 58, wherein the amphipathic lipid is selected from the group consisting of phosphatidylethanolamine (PE), a carbamate-linked uncharged lipopolymer, and aminopropanediol distearoyl (DS).

Claim 70. (Previously presented) The pharmaceutical composition of claim 69, wherein the amphipathic lipid is aminopropanediol distearoyl (DS).

Claim 71. (Previously presented) The pharmaceutical composition of claim 58, wherein the biocompatible hydrophilic polymer is selected from the group consisting of polyalkylether, polylactic and polyglycolic acid families.

Claim 72. (Previously presented) The pharmaceutical composition of claim 71, wherein the biocompatible hydrophilic polymer is polyethylene glycol.

Claim 73. (Currently amended) A pharmaceutical composition for parenteral administration, comprising:

a therapeutically effective amount of a protein or polypeptide selected from the group consisting of Factor VIIa, granulocyte colony-stimulating factor (G-CSF), granulocyte macrophage colony-stimulating factor (GM-CSF), interferon γ , glucagon-like peptide 1 (GLP-1) and Cepaxone glatiramer acetate;

one or more colloidal particles comprising

approximately 1-20 mole percent of an amphipathic lipid derivatized with a biocompatible hydrophilic polymer,

a second amphipathic lipid obtained from either natural or synthetic sources; and

cholesterol,

wherein the protein or polypeptide is non-covalently bound to the one or more colloidal particles and is not encapsulated in the one or more colloidal particles.

Claim 74. (Currently amended) A pharmaceutical composition for parenteral administration, comprising:

a therapeutically effective amount of a protein or polypeptide selected from the group consisting of Factor VIIa, granulocyte colony-stimulating factor (G-CSF), granulocyte macrophage colony-stimulating factor (GM-CSF), interferon γ , glucagon-like peptide 1 (GLP-1) and Cepaxone glatiramer acetate; and

one or more colloidal particles comprising approximately 1-20 mole percent of an amphipathic lipid selected from the group consisting of phosphatidylethanolamine (PE), a carbamate-linked uncharged lipopolymer and aminopropanediol distearoyl (DS), the amphipathic lipid is derivatized with a biocompatible hydrophilic polymer,

wherein the protein or polypeptide is non-covalently bound to one or more colloidal particles, and the protein or polypeptide is not encapsulated in the one or more colloidal particles.